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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/762,530

01/23/2004

Minoru Sano

NPR-135

5543

20374 7590 05/28/2009

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EXAMINER

PRICE, NATHAN R

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

05/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/762,530	Applicant(s) SANO ET AL.	
	Examiner NATHAN R. PRICE	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. This office action is responsive to the amendment filed on September 13, 2007. As directed by the amendment: claims 1 and 3 have been amended, claims 2 and 4-8 have been cancelled, and no new claims have been added. Thus, claims 1 and 3 are presently pending in this application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhard et al. (US 6331174). Reinhard et al. discloses a prefilled syringe (fig. 3A) comprising: a shoulder portion (where barrel turns into nozzle, fig. 3A between elements 1 and 5) provided with a tip 5 (fig. 3A) arranged to be connected to an injection needle 6 (fig. 3A) at a tip thereof and sealed by a cap having a barrier property (protective cap, col. 5, ln. 35); a barrel 1 (fig. 3A) closed by the shoulder portion and having an open proximal end; and a gasket 4 (as labeled in fig. 1, not shown in fig. 3A) inserted adjacent to the open proximal end of the barrel in a fluid-tight manner while being freely slidable (col. 4, ln. 61), a medication (col. 2, ln. 59) being contained inside the barrel, wherein the barrel has a multilayer structure (col. 3, ln. 66 – col. 4, ln. 27; see fig. 3A) in which an innermost layer 10 (fig. 3A) and an outermost layer 9 (fig. 3A) are

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both made of a polyolefin resin (col. 4, ln. 11), and an intermediate layer 14 (fig. 3A) is sandwiched by the innermost layer and the outermost layer and the intermediate layer is composed of at least one layer made of a material excelling in oxygen and/or water vapor barrier property (col. 6, ln. 28-38), and further wherein the intermediate layer is formed up to a vicinity of a surface of the tip (see fig. 3, layer is formed up to “a vicinity” of the tip element 5 and its surfaces), and is not formed in a direction of the proximal end of the barrel from a proximal end of an initial insertion point of the gasket inserted in the barrel (initial insertion point of the gasket, here interpreted as the point at which the gasket must be inserted during assembly of the device, is the rear opening of the syringe barrel; as is evident from fig. 3A, the intermediate layer does not extend proximally past this initial insertion point), an end of the intermediate layer in a cylindrical wall portion of the barrel is formed up to a rim of the shoulder portion (see fig. 3; intermediate layer 14 terminates at the point where the shoulder portion begins), and the shoulder portion formed with the polyolefin resin has a thickness sufficient to exert an oxygen and/or water vapor barrier property (shoulder shown in fig. 3A has a thickness; col. 5, ln. 24-28 describe the material used and the selection of said material based on its barrier properties), **except for** a luer tip, and the intermediate layer composed of at least one layer made of resin.

4. However, Kaufhold, Jr. et al. teaches use of a luer tip in combination with a syringe body (abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Reinghard et al. apparatus such that it comprises a luer tip, as taught by Kaufhold, Jr. et al., for the purpose of providing

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a well-known attachment mechanism commonly used in the art of syringes and injectors to provide sufficient structure for attachment of a needle (abstract).

5. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a resin for the intermediate layer as opposed to the ceramic or glassy materials disclosed by Reinhard et al. to possess the desired barrier characteristics (col. 6, ln. 28-38), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

6. Applicant's arguments filed September 13, 2007 have been fully considered but they are not persuasive.

7. Applicant argues on page 4 of the Remarks that Reinhard "does not disclose a gas permeable intermediate layer." However, Applicant is arguing that which is not claimed. The instant claims require an intermediate layer excelling in a barrier property. Applicant further argues on page 5 of the Remarks that the inner and outer layers of the present invention "are not necessarily a barrier to oxygen or water vapor." However, this feature is also not claimed. Applicant further argues on page 5 of the Remarks that Reinhard only discloses that the inner and outer layers are formed of an appropriate resin, and that the intermediate layer is formed of other materials. Examiner directs Applicant to rejection of claims 1 and 3 above.

8. Applicant argues on pages 6 and 7 of the Remarks that Reinhard discloses the intermediate layer extending from the proximal end of the barrel to the distal end.

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However, Examiner interprets this disclosure to meet the limitations of the current claims, as noted in the rejection above.

9. Applicant argues on page 8 of the Remarks that there is no motivation for a person of ordinary skill in the art to modify the prefilled syringe of Reinhard to include the luer lock of Kaufhold because the luer lock mechanism of Kaufhold is not an integrated part of the barrel. However, Kaufhold is relied upon to support that luer locks are commonly used in the art for catheter tips in order to provide sufficient structure to attach a needle; furthermore, it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN R. PRICE whose telephone number is (571)270-5421. The examiner can normally be reached on Monday-Thursday, 9:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. P./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art
Unit 3763